UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/538,106	03/29/00	MCKEON	HMV-038.02

EXAMINER	
ART UNIT	PAPER NUMBER
1751	5

025181
FOLEY, HOAG & ELIOT, LLP
PATENT GROUP
ONE POST OFFICE SQUARE
BOSTON MA 02109

HM12/0703

DATE MAILED: 07/03/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

Office Action Summary

Application No.	Applicant(s)
09/538,106	McKeon et al
Examiner	**Art Unit**
Anne Holleran	1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☐ Responsive to communication(s) filed on _____.

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-14* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☐ Claim(s) _____ is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☒ Claims *1-14* are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
18) ☐ Interview Summary (PTO-413) Paper No(s). _____
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other:

DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claim 1, drawn to a nucleic acid sequence encoding a p63 cell regulatory protein, classified in class 536, subclass 23.5.

II. Claims 2-10, 11 and 12 drawn to methods for diagnosing malignant carcinoma, detecting onset of cancer, or distinguishing cervical squamous carcinoma, to the extent the methods read on determining the level of a p63 gene product that is a nucleic acid product, classified in classes 435 and 536, subclasses 6 and 24.3, respectively.

III. Claims 2-10, 13 and 14 drawn to methods for diagnosing malignant carcinoma, detecting onset of cancer, or distinguishing cervical squamous carcinoma, to the extent the methods read on determining the level of a p63 gene product that is a protein product, classified in classes 435 and 530, subclasses 7.1 and 387.1, respectively.

2. The inventions are distinct, each from the other because of the following reasons:

Each of inventions II and III is directed to a separate and distinct process. Each of the processes are distinct both physically and functionally and require different steps and use different

products. The methods of group II require the use of polynucleotides, while the methods of group III require the use of antibodies.

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the polynucleotides of invention group I can be used to recombinantly make proteins, a materially different process of using a nucleic acid product than a process of detecting nucleic acid gene products.

3. The claims of groups I or II are each drawn to separate or distinct p63 polynucleotides or to detection of generic p63 polynucleotides. This constitutes recitation of an implied, misjoined Markush group that contains multiple, independent and distinct inventions. Each of the different p63 polynucleotides is independent and distinct because no common structural or functional properties are shared. Accordingly, these claims are subject to restriction under 35 U.S.C. 121.

Upon election of either of groups I or II, Applicant is additionally required to elect a single species from the following groups: **group 1.)** nucleic acid which hybridizes to SEQ ID NO: 1 or detection thereof; **group 2.)** nucleic acid which hybridizes to SEQ ID NO: 2 or detection thereof; **group 3.)** nucleic acid which hybridizes to SEQ ID NO: 3 or detection thereof; **group 4.)** nucleic acid which hybridizes to SEQ ID NO: 4 or detection thereof; **group 5.)** nucleic acid which hybridizes to SEQ ID NO: 5 or detection thereof; **gr up 6.)** nucleic acid which hybridizes to

SEQ ID NO: 6 or detection thereof; **group 7.)** nucleic acid which hybridizes to SEQ ID NO: 7 or detection thereof; **group 8.)** nucleic acid which hybridizes to SEQ ID NO: 8 or detection thereof; **group 9.)** nucleic acid which hybridizes to SEQ ID NO: 9 or detection thereof; **group 10.)** nucleic acid which hybridizes to SEQ ID NO: 10 or detection thereof; **group 11.)** nucleic acid which hybridizes to SEQ ID NO: 11 or detection thereof; **group 12.)** nucleic acid which hybridizes to SEQ ID NO: 12 or detection thereof. Groups 1-12 appear to be separate groups because each polynucleotide appears to be a separate and distinct polynucleotide product. This requirement is not to be construed as a requirement for an election of species, since each of the polynucleotides recited in alternative form is not a member of a single genus of invention, but constitutes an independent and patentably distinct invention.

4. The claims of group III are each drawn to detection of generic p63 polypeptides. This constitutes recitation of an implied, misjoined Markush group that contains multiple, independent and distinct inventions. Each of the different p63 polypeptides is independent and distinct because no common structural or functional properties are shared. Accordingly, these claims are subject to restriction under 35 U.S.C. 121.

Upon election of group III, Applicant is additionally required to elect a single species from the following groups: **group 1.)** detection of a polypeptide encoded by a nucleic acid which hybridizes to SEQ ID NO: 1; **group 2.)** detection of a polypeptide encoded by a nucleic acid which hybridizes to SEQ ID NO: 2; **group 3.)** detection of a polypeptide encoded by a nucleic acid which hybridizes to SEQ ID NO: 3; **group 4.)** detection of a polypeptide encoded by a

nucleic acid which hybridizes to SEQ ID NO: 4; **group 5.)** detection of a polypeptide encoded by a nucleic acid which hybridizes to SEQ ID NO: 5; **group 6.)** detection of a polypeptide encoded by a nucleic acid which hybridizes to SEQ ID NO: 6; **group 7.)** detection of a polypeptide encoded by a nucleic acid which hybridizes to SEQ ID NO: 7; **group 8.)** detection of a polypeptide encoded by a nucleic acid which hybridizes to SEQ ID NO: 8; **group 9.)** detection of a polypeptide encoded by a nucleic acid which hybridizes to SEQ ID NO: 9; **group 10.)** detection of a polypeptide encoded by a nucleic acid which hybridizes to SEQ ID NO: 10; **group 11.)** detection of a polypeptide encoded by a nucleic acid which hybridizes to SEQ ID NO: 11; **group 12.)** detection of a polypeptide encoded by a nucleic acid which hybridizes to SEQ ID NO: 12. Groups 1-12 appear to be separate groups because each polynucleotide appears to be a separate and distinct polynucleotide product. This requirement is not to be construed as a requirement for an election of species, since each of the polynucleotides recited in alternative form is not a member of a single genus of invention, but constitutes an independent and patentably distinct invention.

5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, separate status in the art as shown by their different classification, and because the searches for the groups are not co-extensive, restriction for examination purposes as indicated is proper.

6. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Any inquiry concerning this communication or earlier communications from the Office should be directed to Anne Holleran, Ph.D. whose telephone number is (703) 308-8892. Examiner Holleran can normally be reached Monday through Friday, 9:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, Ph.D. can be reached at (703) 308-3995.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist at telephone number (703) 308-0196.

AcH

Anne L. Holleran
Patent Examiner
June 28, 2001

AC

ANTHONY C. CAPUTA
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600